

# GRAM LUGOL SOLUTION, STABILIZED

CE IVD *In vitro* diagnostic medical device

Classified acc. to Regulation (EU) 2017/746 - Class A device

## Solution containing polyvinylpyrrolidone iodine (PVP-I)

### Solution for use in BioGram 4 Gram bacteria staining kit

#### INSTRUCTIONS FOR USE

<b>BASIC UDI number</b>	385889212HPC4080299MCKA				
<b>EMDN code</b>	W0104080299				
<b>REF Catalog number</b>	<b>Volume</b>	<b>UDI-DI number</b>	<b>REF Catalog number</b>	<b>Volume</b>	<b>UDI-DI number</b>
GLS-OT-100	100 mL	03858888822897	GLS-OT-1L	1000 mL	03858890009248
GLS-OT-250	250 mL	03858888822903	GLS-OT-2.5L	2500 mL	03858890005462
GLS-OT-500	500 mL	03858888822910	GLS-OT-5L	5000 mL	03858892122839



#### Intended use and test principle

Gram staining is a method of differentiating bacterial species and it is commonly known and used in microbiology. It is also one of the most frequently used diagnostic methods in hospital and clinical laboratories. Gram staining differentiates bacteria into two groups: Gram-positive and Gram-negative. That division is based on the two groups' bacterial membrane structural differences, i. e. their capability of retaining the dye. BioGnost's Stabilized Gram Lugol solution enhances that capability. It consists of aqueous solution of stabilized (polyvinylpyrrolidone) iodine (PVP-I) and potassium iodide. During the Gram staining process the solution enables the dye to enter the bacterial cell and create insoluble iodine and primary dye complex. That enables dye retaining and subsequent Gram-positive bacteria identification.

#### Product description

- **GRAM LUGOL SOLUTION, STABILIZED** - Solution for use in microbiology for Gram staining

#### An example of using Gram Lugol solution, stabilized as a component of BioGram 4 kit

#### Additional reagents and materials that can be used in this method

- VitroGnost slides and coverslips for use in histopathology and cytology
- BioGnost's immersion oils, such as Immersion oil, Cedarwood oil, Immersion oils types A and C, FF, 37 or Tropical Grade
- The remaining components of BioGram 4 kit: Gram Crystal Violet 1% solution, Gram Decolorizer solution 2 and Gram Safranin solution
- Saline solution

#### Preparing the sample for staining

- Transfer the sample on a clean glass slide using a sterilized smear loop  
Note: Bodily fluids, discharge, pus, and liquid or solid bacterial culture can be used as samples
- Spread the sample evenly across the glass slide using 1-2 drops of saline solution
- Fix the sample using the Bunsen burner after drying by wriggling the glass slide through the cone of flame for 2-3 times
- Cool the glass slide and begin the process of staining

#### Sample staining procedure

Pour the reagents into glass staining jars (Coplin, Hellendahl or Schifferdecker), return to original bottles after staining. Close tightly. Filter the reagents if necessary.

1.	Stain using Gram Crystal Violet 1% solution	1 min
2.	Pour excessive dye off the section	
3.	Rinse the slide carefully using Gram Lugol solution, stabilized	
4.	Fix the dye by using Gram Lugol solution, stabilized	1 min
5.	Rinse carefully with distilled/demineralized water	5 sec
6.	Treat with Gram Decolorizer solution 2 End the process when the slide turns grey-blue	10-15 sec
	Note: By overly treating with Decolorizer solution, the dye will be washed away from Gram-positive bacteria as well	
7.	Rinse carefully with distilled/demineralized water	5 sec
8.	Treat with Gram Safranin solution	1 min
9.	Rinse carefully with distilled/demineralized water	5 sec
10.	Dry the slide using filter paper or let it dry by air	
11.	Add a drop of immersion oil on the slide	
12.	Examine the slide under immersion lens	

#### Result

Gram-positive bacteria – blue-purple

Gram-negative bacteria – red

#### Limitations

This product is intended for professional laboratory use for diagnostic purposes only. Deviations from the staining procedure described in this Instruction for use may cause differences in staining results.

#### Sample preparation and diagnostics

Use only appropriate instruments for collecting and preparing the samples. Process the samples using modern technology and mark them clearly. Be sure to follow the manufacturer's handling instructions. To avoid errors, staining and diagnosis can only be carried out by qualified personnel. Use a microscope equipped according to medical diagnostic laboratory standards. To avoid an incorrect staining result, it is advised to use a positive and negative control.

If a serious incident occurs during use of this product or as a result of its use, please report it to the manufacturer or authorized representative and competent authority.

### Safety at work and environmental protection

Handle the product in accordance with occupational health and environmental protection guidelines. Used and expired solutions must be disposed of as special waste following national guidelines. Reagents used in this procedure can pose a danger to human health. The examined tissue samples are potentially infectious, and it is necessary to take the measures needed to protect human health in accordance with the guidelines of good laboratory practice. It is mandatory to read and act according to the information and warning signs printed on the product label and in the Safety Data Sheet, which is available on request.

### Storage, stability, and shelf life

Upon receipt, store the product in a dry place and well-closed original packaging at a temperature of +15 °C to +25 °C. Do not freeze or expose to direct sunlight. After first opening, the product can be used until the specified expiry date, if stored properly. The expiration date is printed on the product label.

### References

1. Carson, F. L., Hladik, C. (2009); *Histotechnology: A Self-Instructional Text*, 3<sup>rd</sup> ed., Chicago: ASCP Press
2. Kiernan, J. A. (2008); *Histological and Histochemical Methods*, 4<sup>th</sup> ed., Bloxham: Scion Publishing Ltd

#### Warnings and precautions regarding the materials contained in the product:

*Not a hazardous substance or mixture acc. to Regulation (EZ) br. 1272/2008.*

GLS-IFU\_ENV7, 27.02.2026. IŠP

 Manufacturer	 Batch code	 Consult instructions for use	 European conformity
 Date of manufacture	 Catalogue number	 Caution	 Unique device identifier
 Use-by date	 Temperature limit	 <i>In vitro</i> diagnostic medical device	

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Version	Description / reason for change	Date
7	Revised in acc. to Regulation (EU) 2017/746 - IVDR	27.02.2026.